UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,701	11/30/2001	Henry Yue	PF-0631-2 DIV	5300

27904 7590 10/10/2003

INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.)
3160 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER	
CARLSON, KAREN C	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,701	YUE ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1, claim(s) 1, 2, 17, 18, and 56, drawn to polypeptide having SEQ ID NO: 1.

Group 2, claim(s) 1, 2, 17, 18, and 57, drawn to polypeptide having SEQ ID NO: 2.

Group 3, claim(s) 3-7, 9, 10, 12, 13, 46-55, and 76, drawn to polynucleotide encoding polypeptide having SEQ ID NO: 1.
Group 4, claim(s) 3-7, 9, 10, 12, 13, 46-55, and 77, drawn to polynucleotide encoding polypeptide having SEQ ID NO: 2.

Group 5, claim(s) 8, drawn to transgenic organism comprising polynucleotide encoding polypeptide having SEQ ID NO: 1.
Group 6, claim(s) 8, drawn to transgenic organism comprising polynucleotide encoding polypeptide having SEQ ID NO: 2.

Group 7, claim(s) 11 and 30-45, drawn to antibody against polypeptide having SEQ ID NO: 1.
Group 8, claim(s) 11 and 30-45, drawn to antibody against polypeptide having SEQ ID NO: 2.

Group 9, claim(s) 14-16, drawn to method for detecting polynucleotide using polynucleotide encoding polypeptide having SEQ ID NO: 1.
Group 10, claim(s) 14-16, drawn to method for detecting polynucleotide using polynucleotide encoding polypeptide having SEQ ID NO: 2.

Group 11, claim(s) 19, drawn to method of treatment by administering polypeptide having SEQ ID NO: 1.
Group 12, claim(s) 19, drawn to method of treatment by administering polypeptide having SEQ ID NO: 2.

Group 13, claim(s) 20, drawn to a method of screening agonists of polypeptide having SEQ ID NO: 1.
Group 14, claim(s) 20, drawn to a method of screening agonists of polypeptide having SEQ ID NO: 2.

Group 15, claim(s) 21, drawn to an agonist of polypeptide having SEQ ID NO: 1.
Group 16, claim(s) 21, drawn to an agonist of polypeptide having SEQ ID NO: 2.

Group 17, claim(s) 22, drawn to a method of treatment by administering the agonist of polypeptide having SEQ ID NO: 1.
Group 18, claim(s) 22, drawn to a method of treatment by administering the agonist of polypeptide having SEQ ID NO: 2.

Group 19, claim(s) 23, drawn to a method of screening antagonists of polypeptide having SEQ ID NO: 1.
Group 20, claim(s) 23, drawn to a method of screening antagonists of polypeptide having SEQ ID NO: 2.

Group 21, claim(s) 24, drawn to an antagonist of polypeptide having SEQ ID NO: 1.
Group 22, claim(s) 24, drawn to an antagonist of polypeptide having SEQ ID NO: 2.

Group 23, claim(s) 25, drawn to a method of treatment by administering the antagonist of polypeptide having SEQ ID NO: 1.
Group 24, claim(s) 25, drawn to a method of treatment by administering the antagonist of polypeptide having SEQ ID NO: 2.

Group 25, claim(s) 26, drawn to a method for screening compounds that bind to polypeptide having SEQ ID NO: 1.
Group 26, claim(s) 26, drawn to a method for screening compounds that bind to polypeptide having SEQ ID NO: 2.

Group 27, claim(s) 27, drawn to a method for screening compounds that modulate the activity of polypeptide having SEQ ID NO: 1.
Group 28, claim(s) 27, drawn to a method for screening compounds that modulate the activity of polypeptide having SEQ ID NO: 2.

Group 29, claim(s) 28, drawn to a method of screening for compounds that alter the expression of polynucleotide encoding polypeptide having SEQ ID NO: 1.
Group 30, claim(s) 28, drawn to a method of screening for compounds that alter the expression of polynucleotide encoding polypeptide having SEQ ID NO: 2.

Group 31, claim(s) 29, drawn to a method for assessing toxicity using a polynucleotide encoding polypeptide having SEQ ID NO: 1.
Group 32, claim(s) 29, drawn to a method for assessing toxicity using a polynucleotide encoding polypeptide having SEQ ID. NO: 2.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Groups 3 and 4 are related to the protein of Groups 1 and 2, respectively, by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Groups 1 and 2 are related to the antibodies of Groups 7 and 8, respectively, by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially

different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Groups 3 and 4 and the antibody of Groups 7 and 8 are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The protein of Groups 1 and 2, the DNA of Groups 3 and 4, the antibody of Groups 7 and 8, the agonist of Groups 15 and 16, and the antagonist of Groups 21 and 22 differ in structure and function one from the other and are therefore patentably distinct.

Groups 1 and 2 and Groups 11 and 12, 13 and 14, 19 and 20, 25 and 26, and 27 and 28 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of the methods of Groups 11 and 12, 13 and 14, 19 and 20, 25 and 26, and 27 and 28.

Groups 3 and 4 and Groups 5 and 6, 9 and 10, 29 and 30, and 31 and 32 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as

claimed can be used in a materially different process such as in any one of the methods of Groups 5 and 6, 9 and 10, 29 and 30, and 31 and 32.

The product of Groups 1, 2, 7, and 8 are not used in the method of Groups 5 and 6, 9 and 10, 29 and 30, and 31 and 32. Therefore, Groups 1, 2, 7, and 8 are patentably distinct from Groups 5 and 6, 9 and 10, 29 and 30, and 31 and 32.

The product of Groups 3, 4, 7, and 8 are not used in the method of Groups 11 and 12, 13 and 14, 19 and 20, 25 and 26, and 27 and 28. Therefore, Groups 3, 4, 7, and 8 are patentably distinct from Groups 11 and 12, 13 and 14, 19 and 20, 25 and 26, and 27 and 28.

The methods of Groups 11 and 12, 13 and 14, 19 and 20, 25 and 26, 27 and 28, 5 and 6, 9 and 10, 29 and 30, and 31 and 32 require different products and steps and have different endpoints. Therefore, these groups are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184

O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson Ph.D

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER